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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,465	08/23/2006	Kelly Chibale	02307E-143910US	9767

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1627	

MAIL DATE	DELIVERY MODE
03/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,465	CHIBALE ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 16-19 (in part), drawn to a compound of formula I, where X is CH.

Group II, claim(s) 1-10, 16-19 (in part), drawn to a compound of formula I, where X is N.

Group III, claim(s) 11-12, drawn to a compound of formula III.

Group IV, claim(s) 13, drawn to a compound of formula IV.

Group V, claim(s) 14, drawn to a compound of formula V.

Group VI, claim(s) 15, drawn to a compound of formula VII.

Group VII, claim(s) 20-22, 26-29, 33, drawn to a method of preventing and treating STD comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group VIII, claim(s) 20-22, 26-29, 33, drawn to a method of preventing and treating STD comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group IX, claim(s) 20-21, 23, 26-28, 30, 33, 36-37, drawn to a method of preventing and treating malaria comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group X, claim(s) 20-21, 23, 26-28, 30, 33, 36-37, drawn to a method of preventing and treating malaria comprising administering a pharmaceutical composition

comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group XI, claim(s) 20-21, 24, 26-28, 31, 33, drawn to a method of preventing and treating Leishmaniasis comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group XII, claim(s) 20-21, 24, 26-28, 31, 33, drawn to a method of preventing and treating Leishmaniasis comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group XIII, claim(s) 20-21, 25-28, 32-33, 38, drawn to a method of preventing and treating Chagas' disease comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group XIV, claim(s) 20-21, 25-28, 32-33, 38, drawn to a method of preventing and treating Chagas' disease comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group XV, claim(s) 20-21, 25-28, 32-33, 35, drawn to a method of preventing and treating African sleeping sickness comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group XVI, claim(s) 20-21, 25-28, 32-33, 35, drawn to a method of preventing and treating African sleeping sickness comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group XVII, claim(s) 20-21, 25-28, 32-33, drawn to a method of preventing and treating nagana comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group XVIII, claim(s) 20-21, 25-28, 32-33, drawn to a method of preventing and treating nagana comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group XIX, claim(s) 27-28, 33, drawn to a method of preventing and treating trichomoniasis comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group XX, claim(s) 27-28, 33, drawn to a method of preventing and treating trichomoniasis comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

Group XXI, claim(s) 34, drawn to a method of preventing and treating cancer comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is CH.

Group XXII, claim(s) 34, drawn to a method of preventing and treating cancer comprising administering a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier, where X is N.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-XXII lack unity because the shared common technical feature is not a contribution over the prior art. Since it is well known in the art, it cannot be considered a special technical feature. In the instant case, the shared common technical feature is a compound of formula I.

Unity of invention links the various inventions together by sharing a common special technical feature in each invention. However, when the special technical feature is not a contribution over the prior art, the various inventions may be restricted from each other. In the instant case, unity of invention does not exist because the shared common technical feature is disclosed in Greenbaum D.C. (Synthesis and Structure-Activity Relationships of Parasiticidal Thiosemicarbazone Cysteine Protease inhibitors against Plasmmodium falciparum, Trypanasoma brucei and Trypanosoma cruzi, J. Med. Chem., May 2004, vol. 47 no. 12, pages 3232-3219, page 3213); and Du X (Synthesis and Structure, J. Med. Chem., May 2002, vol. 45 no. 13, pages 2695-2707, page

2696).. Therefore, restriction between the composition and method claims is proper. See MPEP 1850 and 37 CFR 1.475.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Species Election

This application contains claims directed to more than one species of the generic invention.

The species are as follows:

1) a single disclosed compound of formula I.

2) a single disclosed compound of formula III.

3) a single disclosed compound of formula IV.

4) a single disclosed compound of formula V.

5) a single disclosed compound of formula VII.

If applicant elects Group I-II, VII-XXII, applicant is further required to elect a single disclosed compound of formula I from subsection 1.

If applicant elects Group III, applicant is further required to elect a single disclosed compound of formula III from subsection 2.

If applicant elects Group IV, applicant is further required to elect a single disclosed compound of formula IV from subsection 3.

If applicant elects Group V, applicant is further required to elect a single disclosed compound of formula V from subsection 4.

If applicant elects Group VI, applicant is further required to elect a single disclosed compound of formula VII from subsection 5.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature for the same reasons as stated above

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will then be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a)

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex; 2) the application is being prosecuted pro se; or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/YONG S. CHONG/
Primary Examiner, Art Unit 1617

YSC